



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,089	10/02/2003	Jean-Michel Bernardon	016800-437	8389
21839	7590	03/25/2005	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			HUANG, EVELYN MEI	
POST OFFICE BOX 1404			ART UNIT	
ALEXANDRIA, VA 22313-1404			PAPER NUMBER	

1625

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,089	<b>Applicant(s)</b> BERNARDON ET AL.	
	<b>Examiner</b> Evelyn Huang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-28 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 21-28 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☒ Certified copies of the priority documents have been received in Application No. 09/002,040.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 21-28 are pending. Claims 1-20 have been canceled according to the amendment filed on 10-26-2004.

#### ***Priority***

2. The amendment inserting a specific reference to the prior application(s) in the first sentence of the specification is acknowledged. However, the abandoned status of 09/788469 should also be recited.

#### ***Claim Rejections - 35 USC § 112***

3. The rejection for Claims 21-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant method of treatment of a dermatological condition embraces all the dermatological conditions not described in the specification, and it reaches out to as yet unidentified dermatological conditions, the description is not found in the specification.

The 'dermatological condition comprises at least one....' of claim 22 embraces all the conditions not described in the specification. 'other skin atrophy' embraces all the skin atrophy not described in the specification, including the as yet unidentified skin atrophy, a description is not found in the specification.

The 'dermatological condition comprising a inflammatory and/or immunoallergic keratinization disorder' of claims 23, 24 embraces all the conditions, and reaches out to an as yet unidentified inflammatory and/or immunoallergic keratinization disorder, the description of which is not found in the specification.

***Claim Rejections - 35 USC § 112***

4. The rejection for Claims 21-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is replaced by the following rejection:

Claims 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 22, 'comprises at least one' in 'dermatological condition comprises at least one...' is open-ended and is therefor indefinite.

b. Claims 23, 24, 'comprising' in 'a dermatological condition comprising an inflammatory and/or immunoallergic keratinization disorder' is open-ended and is therefore indefinite.

c. Claims 25-28, 'comprises' in 'the dermatological condition comprises' is open-ended and is therefore indefinite.

***Claim Rejections - 35 USC § 112***

5. The rejection for Claims 21-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record.

Applicants contend that pages 1-5 of the specification teach utility of the compounds without requiring that the use be linked to affinity to a particular receptor.

However, in view of the *only* working example (Example 25) in the specification which describe the procedure for evaluating the retinoid antagonist activity, one of ordinary skill in the art would conclude that the inventive compounds are retinoid antagonists, thereby useful in treating conditions requiring a retinoid antagonist.

Applicants maintains that the Examiner states that a retinoid receptor antagonist compound would counteract the retinoic acid effects is erroneous as Apfel concludes that the retinoid counteracts RA effects in some but not other functional systems.

Art Unit: 1625

On the contrary, the fact that it counteracts RA effects in some systems reinforces the high degree of unpredictability in the art and point to the lack of support for the instantly claimed method for treatment of *any* dermatological condition comprising an inflammatory and/or immunoallergic keratinization disorder, especially when these conditions/disorders are not fully described or have not been identified at the time of the invention.

Applicants submit that Charpentier et al. contradict the Examiner's conclusion. Two of the compounds reported there, 2 and 15, were tested as antagonists in the F9 cell differentiation test and one of these, compound 15, exhibited antagonist activity. Yet compounds 2 and 15 exhibited moderate and high affinities for RARY, respectively, while they were both inactive when tested for their ability to induce differentiation of F9 cells as estimated by plasminogen activator (PA) secretion. Compound 15 also showed RARa binding affinity and high RAR binding affinity. Thus, it is clear that a retinoid can exhibit antagonist activity in the model described in instant Example 25 while still having binding affinity to RARS.

Applicants appear to conclude that a retinoid antagonist would not have binding affinities to RARS. On the contrary, Charpentier et al. do not contradict the Examiner's conclusion. It is well recognized in the art that the binding affinity to the receptors does not distinguish whether the compound is an agonist or an antagonists. Indeed, the results of Charpentier point to the fact that the binding affinities and the biological activities do not strictly correlate. Therefore one of ordinary skill in the art has little basis to extrapolate the results to other structurally remote compounds.

It is submitted that subjecting a species to well known tests for binding activities and affinities is routine experimentation. Even though some of the compounds may be inactive, some inoperable species are allowed. In vivo experiments are not required.

However, the claims are directed to a genus of compounds of diverse structures, including those wherein substituents are further substituted with multiple substituents, which are structurally removed from the exemplified compounds. Because of the high degree of unpredictability in the art, one of ordinary skill in the art would have no basis to extrapolate the results to compounds structurally dissimilar to the examples, and expect that the variety of these substituents embraced by the claims would share the same biological activities. While some experimentation is permitted and every claimed embodiment need not be shown to possess the

Art Unit: 1625

asserted activity, there should be a showing commensurate in scope with the claims. As stated in *In re Cavallito* 127, USPQ 202, “where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds, there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful....an applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others”.

Applicants conclude that antagonist activity does not preclude retinoid activity.

It is possible that a compound may be agonist and antagonist under different conditions. However, there is no teachings and guidance on when the compound is an agonist and when it is an antagonist in the specification, without which one of ordinary skill in the art would not be able to use the invention as claimed without undue experimentation.

### ***Conclusion***

6. The subject matter of claims 25-28 is allowable, since they are not subjected to the 112 (1) written description and enablement rejection.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

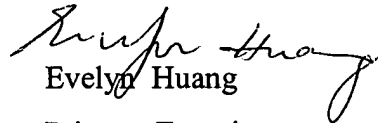
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1625

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

Art Unit 1625